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UNITED STATES DISTRICT COURT FOR THE

NORTHERN DISTRICT OF CALIFORNIA

MOLLY BROWN, PARSA MILLER, and LAUREN MORGAN as individuals, on behalf of themselves, the general public and those similarly situated,

Plaintiffs,

v.

NATURE'S PATH FOODS, INC.,

Defendant.

CASE NO. 4:21-cv-05132-HSG

PLAINTIFFS' SUPPLEMENTAL BRIEF PURSUANT TO ECF NO. 41

HON. HAYWOOD S. GILLIAM, JR.

I. INTRODUCTION

Nature's Path has submitted as "supplemental authority" an FDA webpage that is not actually "authority" at all. The Supreme Court has told district courts not to entertain purported agency regulatory interpretations unless the regulation it interprets is "genuinely ambiguous." Here it is not. Nevertheless, even were the Court to consider the FDA webpage, and take it at face value, it is irrelevant to the questions of liability or preemption as to any of Plaintiffs' claims in this case. Both it, and the regulation on which it is based—21 C.F.R. § 101.13(o)—relate solely to the FDA's process for "determining compliance" for nutrient content claims. This, of course, presumes that the regulations *allow* the nutrient content claim in the first place. If, as Plaintiffs allege here, other regulations *prohibit* the claim at issue, then the question of how the FDA will determine compliance for that claim never enters the picture.

Plaintiffs allege that separate regulations—which the proffered webpage does not mention or discuss—do prohibit Nature's Path from stating a nitrogen-based protein quantity figure *alone* on the front of its package. In particular, 21 C.F.R. § 101.9(c)(7)(i) prohibited Nature's Path from making *any protein claim whatsoever* on its front package because it failed to provide a percent daily value (%DV) for protein in the nutrition facts panel (NFP). Section 101.13(i)(3) separately prohibited Nature's Path from stating the "amount or percentage of a nutrient" if doing so was "false or misleading in any respect." Plaintiffs plausibly allege, and the FDA agrees, that "protein quantity *alone* can be *misleading* on foods that are of *low protein quality*." 58 Fed. Reg. 2079 at 2101-2 (emphases added). The FDA webpage does not mention these regulations, nor does anything it states contradict Plaintiffs' proffered interpretation of them. Accordingly, it does not advance Nature's Path's preemption arguments, nor help it overcome the strong presumption against preemption.

II. ARGUMENT

A. The FDA Webpage is Not "Authority" At All.

Nature's Path submitted the FDA webpage as "supplemental authority," although it is no such thing. In *Kisor*, the Supreme Court admonished lower courts for abdicating their responsibility to interpret regulations in favor of deferring to statements from an agency. *Kisor v.*

Wilkie, 139 S. Ct. 2400 (2019). Under *Kisor*, a court cannot even evaluate a purported agency interpretation unless, after deploying all the interpretative methods in the "legal toolkit," the court finds that the regulation is "genuinely ambiguous." *Id*. at 2414-15. This includes examining the regulation's "text, structure, history, and purpose" before giving up. *Id. Kisor* makes clear that "genuine ambiguity" is extremely rare. *Id*. "[A] court cannot wave the ambiguity flag just because it found the regulation impenetrable on first read." *Id.* at 2415. "[H]ard interpretive conundrums, even relating to complex rules, can often be solved." *Id.*

Here, § 101.13(o), which is what the webpage purports to interpret, is not "genuinely ambiguous." It provides that "compliance with requirements for nutrient content claims …will be determined using *the* analytical methodology [singular] prescribed for *determining compliance* with nutrition labeling in § 101.9." This does not refer to the multiple testing methodologies (plural) described in § 101.9 to *measure* nutrients; rather, it incorporates by reference *the* analytical methodology in § 101.9 the FDA uses for *determining compliance*—i.e., § 101.9(g), which states "Compliance with this section shall be determined as follows . . ." and then sets forth the 12-sample size requirement, recordkeeping obligations, and the like. Even Nature's Path itself argued in its opening brief that this is all § 101.13(o) means, contending that it "requires product testing of at least twelve samples." ECF 18 at 3.[1]

B. The FDA Webpage is Irrelevant to Plaintiffs' UCL Unlawful Prong Claim.

Plaintiffs' UCL unlawful prong claim alleges that Nature's Path violated the Sherman Law (which adopts the FDA regulations), by making a protein claim on the front label without providing a %DV for protein in the NFP. ECF 1 at ¶¶ 32-47, 114. Section 101.9(c)(7)(i) is clear: if a product makes a "protein claim" the manufacturer "*shall*" state the %DV inside the NFP using the Protein Digestibility Corrected Amino Acid Score (PDCAAS). The converse is necessarily true—without a %DV, a manufacturer *shall not* make *any* protein claim. Because Nature's Path's products *never* provided a %DV on the back, its front label protein claims were *always* unlawful per se. Nothing in the FDA webpage is to the contrary.

[1] Even were the regulation "genuinely ambiguous," *Kisor* holds that courts can defer only to "the agency's authoritative or official position." 139 S. Ct. at 2416. The webpage is not an official agency position and is not even binding on the FDA itself. 21 C.F.R. § 10.85(d).

Nature's Path concedes that this claim parallels the regulations and, thus, is not expressly preempted. *See* ECF 26 at 7. It argues only that the claim is impliedly preempted under *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). ECF 18 at 10-11. As Plaintiffs explained in their original brief, this Court and other "courts in this District [] routinely reject the argument that the Court's reasoning in *Buckman* justifies preemption of food labeling claims under the Sherman Law." *Vassigh v. Bai Brands LLC*, 2015 U.S. Dist. LEXIS 90675, at *13 (N.D. Cal. July 13, 2015) (Gilliam, J.) The FDA webpage provides no reason to deviate from that holding.

C. The FDA Webpage Is Irrelevant to Plaintiffs' UCL Fraud Prong and CLRA Claims.

Plaintiffs' fraud prong and CLRA claims allege that Nature's Path's front labels are also misleading in violation of parallel state and federal requirements. In particular, § 101.13(i)(3) prohibits any statement about the "amount or percentage of a nutrient" like protein on the front label if it is "false or misleading in any respect." Nature's Path's standalone, nitrogen-based "10g Protein" claim is misleading because it fails to account for the product's poor quality protein, which is deficient in certain amino acids essential to human protein synthesis. At best, only six grams of its protein are *actually usable by the human body. See e.g.*, ECF 23 at 5. The FDA has explicitly acknowledged in published guidance that stating "protein quantity *alone* can be *misleading* on foods that are of *low protein quality*." 58 Fed. Reg. 2079 at 2101-2 (emphases added). Nothing in § 101.13(o) or the FDA webpage is to the contrary.

D. The FDA Webpage Does Not Create an Automatic Right to Make Standalone, Nitrogen-Based Protein Quantity Claims.

In all likelihood, Nature's Path will argue that since the FDA webpage states it can use nitrogen testing to "determine compliance" for a front label protein claim, it is necessarily authorized to make a nitrogen-based claim, and any state law prohibiting it from doing so is preempted. *See Reid v. Johnson & Johnson*, 780 F.3d 952, 962 (9th Cir. 2015) ("The preemption analysis . . . turns on whether the statement is authorized by FDA regulations."). But such an expansive reading of this webpage (and § 101.13(o)) does not withstand scrutiny.

First, it is clear that the webpage does not *authorize* a manufacturer to make any claims at all. The webpage quotes § 101.13(o)—the *compliance* regulation—notes that § 101.9(c)(7)

references both the nitrogen and PDCAAS methods for calculating protein, and then concludes that "Determination of compliance for protein nutrient content claims will be based on . . . either of the methods mentioned above." ECF 40-1 at 14. But the whole concept of "determining compliance" presupposes that the claim is *already authorized* under the other nutrient content claim regulations. Indeed, § 101.13(b) makes clear that a nutrient content claim "may not be made on the label" if it violates *any* of the provisions of § 101.13. Nothing on the webpage says that manufactures are now absolved from meeting these other nutrient content claim regulations, or automatically satisfy them simply by using a testing methodology referenced in § 101.9(c). The regulations still prohibit stating any protein claim without a %DV in the NFP or stating the amount of a nutrient if it is misleading in any respect—they did not vanish. Only once a claim satisfies all of these other provisions does § 101.13(o) come into play.

Second, if Nature's Path's argument were correct, then *any* information provided in the NFP would *automatically* qualify as an authorized nutrient content claim because it is necessarily supported by a testing methodology referenced in § 101.9(c). It would not matter whether it met any of the other, stricter regulations in § 101.13 governing nutrient content claims. But the FDA went out of its way to specify that this information did *not* automatically qualify as nutrient content claims. Section 101.13(c) makes clear that information stated in the NFP is "not subject to the requirements" for nutrient content claims, ***but*** "[i]f such information is declared *elsewhere* on the label or in labeling, it is a nutrient content claim and *is subject to the requirements for nutrient content claims*." (emphasis added). "A regulation cannot be susceptible to a construction that ignores or renders meaningless parts of its language." *Mont. Air Chapter No. 29, Ass'n of Civilian Technicians, Inc. v. Fed. Labor Relations Auth.*, 898 F.2d 753, 762 (9th Cir. 1990). Nature's Path's interpretation of this webpage would render § 101.13(c) and many of the other provisions of § 101.13 meaningless.

Alternatively, Nature's Path may argue that this webpage means that stating a protein quantity on the front of a package based on the nitrogen method is *automatically* not misleading under § 101.13(i)(3). But this too is wrong. The webpage never says that (or even mentions the term "misleading"), and, as Plaintiffs quoted above, the FDA has said the *opposite* in the Federal

Register. Instead, the question of whether a standalone nitrogen quantity is misleading turns on the *quality* of the protein at issue. It is not misleading on high quality proteins that provide 100% of the stated amount. It is misleading if the protein is low quality and deficient in certain essential amino acids such that a portion of the protein is wasted. This requires a case-by-case determination, which is precisely what § 101.13(i)(3) contemplates, not a blanket rule stating that nitrogen testing is either always allowed or always prohibited for nutrient content claims. As a result, the fact that this webpage states that nitrogen testing can be used to determine compliance for an authorized protein content claim is not surprising. There are many instances where nitrogen testing by itself may be authorized, just not on Nature's Path's products.

E. The FDA Webpage Supports Plaintiff's Proposed Remedies.

Plaintiffs' legal claims do not depend on Nature's Path making any alternative statement on the label. It was prohibited from making the claim it did because it failed to provide a %DV for protein on the back, and because stating protein quantity alone was misleading due to its low quality protein sources. Nevertheless, Plaintiffs have proposed various ways that the regulations would authorize Nature's Path to make a non-misleading protein content claim consistent with § 101.13(i)(3) (assuming, of course, it provides a %DV in the NFP). These options include stating protein based solely on the PDCAAS method or by using some combination of both the nitrogen and PDCAAS methods (e.g., "10g total protein, 6g digestible protein").

Nature's Path has balked at these proposed remedies, arguing that that PDCAAS is "limited" to calculating "the daily value percentage to be included on the back label only" (ECF 26 at 2) and that it is expressed only as a "score" and cannot be used to determine "the number of protein grams." (ECF 19 at 2). The FDA webpage quashes both arguments. The webpage confirms that PDCAAS is *not* limited to the back; it can be used to determine compliance for a claim on the front (again, assuming the claim was authorized in the first instance). *See* ECF 40-1 at 14. It also confirms that PDCAAS can be used to "determin[e] the number of grams of protein in a serving" (i.e., what the regulations call the "corrected amount of protein (gram) per serving" in § 101.9(c)(7)(ii)). *Id*. Although this relates only to the question of the scope of injunctive relief, as opposed to liability or preemption, it clearly supports Plaintiffs' proposed remedies.

Dated: February 3, 2022.

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